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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Erik D. Olson, Esq.
Jon P. Devine, Jr., Esq.
Aaron Colangelo, Esq.
Dr. Jennifer Sass
Natural Resources Defense Council
1200 New York Avenue, NW, Suite 400
Washington, DC 20005

Dear Messrs. Olson, Devine, Colangelo, and Dr. Sass:

Thank you for your letter of July 7, 2003, to Assistant Administrator Stephen Johnson, asking that EPA expand the scope of issues being considered at the upcoming meeting of the FIFRA Scientific Advisory Panel (SAP) on atrazine. He has asked me to reply on his behalf. As discussed below, I do not believe that any additional charges to the SAP would be appropriate for the July 17 meeting. Nonetheless, I recognize there is some disagreement regarding interpretation of the available data – particularly with regard to the meaning and importance of the amphibian data – and we will bring your views to the attention of the SAP. In addition, we are committed, of course, to examining new data relating to atrazine to be certain that we fully understand and fairly assess the full range of any potential risks, and in doing so, we look forward to working with you and other stakeholders in the future.

In your letter, you argue that the August 2002 amendment to the Consent Decree in *NRDC v. Whitman* compels EPA to place before the SAP a broader set of issues than covered by our current charge. The amendment to the Consent Decree requires EPA to present to the SAP data concerning atrazine exposure and prostate or other cancers in humans. Given the timing requirements in the Consent Decree pertaining to the issuance of a revised atrazine IRED and the linkage between the revised IRED and the SAP review, we do not believe we are under an obligation to submit data to the SAP received by EPA after February 28, 2003. Further, EPA does not interpret the Consent Decree as requiring EPA to revisit cancer issues already decided by the SAP in the absence of new, timely-submitted data. We believe we have met the terms of the amendment to the Consent Decree by bringing to the SAP new information relating to the incidence of prostate cancer in the workers at the St. Gabriel facility. While we recognize that there are several cancer epidemiology studies underway or in press that may shed new light on whether atrazine exposure could cause human cancer, the results of these new studies are not yet available. Therefore EPA did not think it appropriate to ask the SAP to consider the body of old,

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generally negative or inconclusive epidemiology studies involving atrazine and types of cancer other than prostate cancer. I note that EPA did point out to the SAP that information on other cancers in humans is being developed, and gave estimates of when those analyses would be completed. We also indicated that should such information raise issues about the carcinogenic potential of atrazine, we might return to the SAP for another review.

In addition to this general concern, you suggested several specific additions to the SAP's charge for the July 17 meeting. The first would be to ask the SAP the following question: "[I]s there sufficient evidence for the carcinogenicity of atrazine in experimental animals?" This issue was the subject of the June 2000 SAP, and evidence of carcinogenicity in animals was addressed during that meeting. EPA has not received any new data indicating that any tumors other than mammary tumors in rats would be induced by atrazine. We think that the issue has been addressed in the report of the SAP, which can be found at:
http://www.epa.gov/scipoly/sap/2000/index.htm#june

Your second suggested addition was to ask whether "the mechanism of action in animals [is] sufficiently understood to determine whether animal tumors are or are not likely to be relevant to humans in general? ...", and in particular whether *in vitro* aromatase induction by atrazine is a possible alternative mode of action leading to cancer. EPA raised the issue of other modes of action leading to tumor formation in mammary glands of rats in the June 2000 SAP, and the SAP report concluded that neuroendocrine effects, rather than aromatase or other mechanisms, were the primary mode of action by which atrazine causes mammary tumors in rodents. EPA does not regard either the amphibian or the in vitro data concerning aromatase received since the June 2000 SAP as adequate to warrant revisiting this issue. The available amphibian data do not demonstrate induction of aromatase, and the in vitro data alone are not sufficient to show an aromatase mechanism that is operative in vivo in humans. However, EPA's Office of Research and Development (ORD) National Health and Environmental Effects Laboroatores (NHEERL) is currently conducting a detailed investigation of aromatase activity in response to atrazine treatment in rats. As additional data become available, EPA will certainly review those data and will seek advice from the SAP, if new information warrants further review of this issue.

Your third suggestion is to ask the SAP whether several studies concerning atrazine's effects on the endocrine system during early life stages could affect susceptibility to cancer later in life. EPA has reviewed all of the cited studies and generally agrees the mammal data indicate that exposure to atrazine early in life is capable of causing neuroendocrine system effects and that these effects are relevant to humans. We have used these data in our human health risk assessment for atrazine. EPA, however, does not think that any of these studies, including the Birnbaum/Fenton (2003) study, demonstrated a relationship between increased susceptibility to cancer later in life and exposure to atrazine early in life. Moreover, EPA would note that the Birnbaum/Fenton (2003) study has not been finished or published, and we believe that it is premature to ask the SAP to consider it. Finally, we do not regard the amphibian data as relevant to human cancer assessment.

Your fourth suggestion is to ask the SAP's views on several additional epidemiology studies: Donna et al. on triazines and ovarian cancer, Dr. Alavanja's report on results from the

Agricultural Health Study on female pesticide applicators and ovarian cancer, and Mills (2003) study on simazine and prostate cancer. EPA previously considered the study by Donna et al., and concluded that it did not demonstrate a link between triazine exposure and ovarian cancer and this analysis was presented and accepted by the SAP in June 2000. Dr. Alavanja's report is incomplete and not ready for review. More definitive results on ovarian cancer from the ongoing Agricultural Health Study are expected shortly and they will supplant these two studies. The third study by Mills on simazine, as well as Dr. Alavanja's report was received after February 28, 2003.

Finally, we note that EPA has reviewed all of the studies cited in your letter and that nearly all have been included among the materials provided to the SAP for either the upcoming meeting or the June 2000 or June 2003 meetings on atrazine.

We look forward to your participation in the public meeting of the SAP this Thursday. If we can be of any further assistance before then, please feel free to contact Steven Knott at (202) 564-0103.

Sincerely yours,

James Jones, Director,
Office of Pesticide Programs

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